K012301

SEP 1 9 2001

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director, Clinical Affairs
Date of Preparation:	July 19, 2001
Device Name:	
Trade:	IMMULITE® 2000 Digoxin
Catalog Number:	L2KDI2 (200 tests), L2KDI6 (600 tests)
CFR:	A digoxin test system is device intended to measure digoxin, a cardiovascular drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.
Common:	Reagent system for the determination of digoxin in serum and plasma.
Classification:	Class II device, KXT (21 CFR 862.3320)
Panel:	Clinical Toxicology
CLIA Complexity Category:	We believe the category to be moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration Number:	DPC's Registration Number is 2017183

Substantially Equivalent Predicate Device: IMMULITE® Digoxin (K914833)

Description of Device: IMMULITE® 2000 Digoxin is a solid phase, chemiluminescent enzyme-labeled competitive immunoassay for use with the IMMULITE® 2000 Automated Analyzer.

Intended Use of the Device:

IMMULITE® 2000 Digoxin is a solid-phase, chemiluminescent enzyme-labeled competitive immunoassay for use with the IMMULITE® 2000 Automated Analyzer and is designed for the quantitative measurement of digoxin in serum or heparinized plasma, as an aid in monitoring the therapeutic administration of this cardioglycoside, while avoiding toxicity.

Technology:

IMMULITE® 2000 Digoxin is a solid-phase, chemiluminescent enzyme-labeled immunoassay. The solid phase is a polystyrene bead coated with a monoclonal murine anti-digoxin antibody.

The patient sample and alkaline phosphatase-conjugated digoxin are simultaneously introduced into the Reaction Tube containing the bead, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, digoxin in the sample competes with the enzyme-labeled digoxin for a limited number of antibody binding sites on the bead. Unbound enzyme conjugate is then removed by a centrifugal wash, after which substrate is added and the Reaction Tube is incubated for a further 5 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is inversely proportional to the concentration of digoxin in the sample.

IMMULITE® Digoxin is a solid-phase, chemiluminescent enzyme-labeled immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with a monoclonal murine anti-digoxin antibody.

The patient sample and alkaline phosphatase-conjugated digoxin are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, digoxin in the sample competes with the enzyme-labeled digoxin for a limited number of antibody binding sites on the bead. Unbound enzyme conjugate is then removed by a centrifugal wash, after which substrate is added and the Test Unit is incubated for a further 5 minutes.

Technology (continued):

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - is inversely proportional to the concentration of digoxin in the sample.

Performance Equivalence:

Diagnostic Products Corporation asserts that IMMULITE® 2000 Digoxin produce substantially equivalent results to other commercially marketed digoxin assays, such as IMMULITE® Digoxin.

Method Comparison:

The IMMULITE® 2000 Digoxin procedure was compared to a commercially available assay, IMMULITE® Digoxin, on 97 samples, with digoxin concentrations ranging from approximately 0.5 to 6.1 ng/mL. Linear regression analysis yielded the following statistics:

(IMMULITE 2000) = 0.94 (IMMULITE) + 0.097 ng/mL r = 0.977

Means: 1.4 ng/mL (IMMULITE 2000)
1.4 ng/mL (IMMULITE)

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE® 2000 Digoxin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 9 2001

Edward M. Levine, Ph.D.
Director, Clinical Affairs
Diagnostic Products Corporations
5700 West 96th Street
Los Angeles, CA 90045-5597

Re: k012301
Trade/Device Name: Immulite® 2000 Digoxin
Regulation Number: 21 CFR 862.3320
Regulation Name: Digoxin test system
Regulatory Class: Class II
Product Code: KXT
Dated: July 19, 2001
Received: July 20, 2001

Dear Dr. Levine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012301
Device Name: IMMULITE® 2000 Digoxin

Indications For Use: The IMMULITE® 2000 Digoxin assay is for *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer – for the quantitative measurement of digoxin in serum or heparinized plasma, as an aid in monitoring the therapeutic administration of this cardioglycoside, while avoiding toxicity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012301

[X] Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)